



UNITED STATES DEPARTMENT OF COMMERCE
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Washington, D.C. 20231

JUN 12 1991

#16

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. Re. 32,969 issued June 27, 1989, reissue of U.S. Patent No. 4,540,568 issued September 10, 1985, was filed on May 28, 1991, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application has been subject to a regulatory review period within the meaning of 35 USC § 156(g) before its commercial marketing or use. Since a determination has not been made whether the patent in question claims a product which is subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 USC § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 USC § 156.

for *Manuel Antonakis*
Charles E. Van Horn
Patent Policy & Programs Administrator
Office of the Assistant Commissioner for Patents

cc: Franklin D. Wolffe
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